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EXAMINER	
COOK, REBECCA	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/899,704
Filing Date: July 05, 2001
Appellant(s): SCHNELLMANN ET AL.

Benjamin Aaron Adler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 24, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is deficient. Appellants recite that the present invention was designed to test whether pharmacological concentrations of L-ascorbic acid phosphate can promote cellular recovery after injury induced by halocarbon nephrotoxicant such as dichlorovinyl-L-cysteine. However, the independent claims recite a method of recovering cellular functions following injury broadly using ascorbic acid or a salt of ascorbic acid. Dependent claims 3 recites wherein the ascorbic acid is L-ascorbic acid phosphate. Dependent claim 12 includes wherein the injury is selected from a group that includes halogenated hydrocarbon-induced nephrotoxicity and only dependent claim 13 is limited to wherein the injury is caused by a halogenated hydrocarbon when it is dichlorovinyl-L-cysteine.

Appellants current independent claims 1, 11 and 15 do not recite halogenated hydrocarbon-induced nephrotoxicity. Appellants indicate in their Brief that the claims

stand or fall together. Thus, the above do not constitute a critical feature of the method claimed because the limitation is not applied to all of the claims.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that this grouping of claims stands or falls together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,711,780	Fahim	12-1987
5,230,996	Rath et al	7-1993

Nowack, G et al, Toxiciology and Applied Pharmacology, 1997, 145 (1) , 175-183

Saika et al, Graefes Archive for Clinical and Experimental Ophthalmology, 1993 Apr, 231 (4(221-7.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4, 11-13, 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,711,780 (Fahim), 5,230,996 (Rath), Saika et al or Nowak et al.

Each reference discloses that ascorbic acid phosphate or ascorbic acid promote recovery of cellular functions and wound healing such as proliferation following injury, including eye injury, that is caused by a variety of conditions, including toxic substances. Dependent claims differ over the references in reciting ascorbic acid concentration and a specific toxic substance. However, once a method of using a compound is known to treat injury, no unobviousness is seen in an injury caused by a specific toxic substance. Furthermore, once a method of using a compound is known it is within the skill of the artisan to determine the optimum concentration.

Fahim (abstract, column 1, lines 53-59, column 2, lines 25-45) discloses a composition containing ascorbic acid or its salts and that it is used to stimulate cell proliferation following injury. Appellants argue that there is no suggestion or motivation in Fahim to use L-ascorbic acid phosphate alone to recover mitochondrial function, Na+-K+-ATPase protein expression, Na+-K+-ATPase protein activity and active Na+ transport. This is not persuasive. The independent claims recite "ascorbic acid or a salt of ascorbic acid" and only claim 3 recites L-ascorbic acid phosphate. Furthermore, Fahim (column 1, line 58-59) discloses that "ascorbic acid, sodium ascorbate or the like" may be used, which would include the L-ascorbic acid phosphate of claim 3.

Furthermore, the instant "comprising" language of the claims does not limit the claims to only ascorbic acid or a salt of ascorbic acid.

Additionally, the claims recite that the cellular functions are selected from the group consisting of "**proliferation** [emphasis added], mitochondrial function, Na+-K+-ATPase protein expression, Na+-K+-ATPase protein activity and active Na+ transport" and Fahim teaches (abstract) that his composition comprising vitamin C stimulates cell proliferation.

Rath (column 2, lines 37-41, column 4, lines 31-34, 63-65, column 5, line 18, column 7, lin3 23, column 9, lines 6-15, 35-38) discloses a composition comprising ascorbate and that it is useful in transplantation wherein tissue damage such as by oxidation and vessel injury results in occlusion of blood vessels in the transplant, in the treatment of diabetic angiopathy and increasing cellular uptake in the presence of high serum levels of glucose. It would be obvious to one of ordinary skill that preventing tissue damage of a transplant would prevent damage to the mitochondria, the treatment of angiopathy would involve the cellular function proliferation and increasing cellular uptake of glucose would involve mitochondrial function.

Appellants argue that there is no suggestion or motivation in Rath to use L-ascorbic acid phosphate alone to recover mitochondrial function, Na+-K+-ATPase protein expression, Na+-K+-ATPase protein activity and active Na+ transport. This is not persuasive. The independent claims recite "ascorbic acid or a salt of ascorbic acid" and only claim 3 recites L-ascorbic acid phosphate. Furthermore, Rath (column 4, lines 63-65) discloses that "the term 'ascorbate' includes any pharmaceutically acceptable salt of ascorbate," which would include the L-ascorbic acid phosphate of claim 3.

Furthermore, the instant "comprising" language of the claims does not limit the claims to only ascorbic acid or a salt of ascorbic acid. Moreover, Rath discloses (column 5, line 18) that ascorbate can be used alone.

Additionally, the claims recite that the cellular functions are selected from the group consisting of "**proliferation** [emphasis added], mitochondrial function, Na+-K+-ATPase protein expression, Na+-K+-ATPase protein activity and active Na+ transport" and Rath teaches that his composition comprising vitamin C prevents tissue damage of a transplant, which would prevent damage to the mitochondria (column 4, lines 31-34) and minimizes vessel injury (column 6, lines 30-40, column 7, line 23), the treatment of angiopathy, which would involve the cellular proliferation (column 9, line 14) and increasing cellular uptake of glucose, which would involve mitochondrial function (column 9, lines 35-38).

Saika et al disclose that L-ascorbic acid 2-phosphate (P-Asc) has a therapeutic role in the repair of corneal alkali burns (abstract). Appellant argues that Saika et al only teach an effect based on the presence of basal lamina under new epithelia. This is not persuasive. Saika et al disclose basal lamina under new epithelia in the corneas treated with ascorbate or P-Asc, but not in controls and says that the observations support the theory that P-Asc may have a therapeutic role in the repair of corneal alkali burns. This meets the claims limitation of recovering cellular functions following injury (alkali burn) wherein the cellular function is proliferation (all independent claims) and wherein the injury is burns (claim 12).

Nowak et al disclose that L-Ascorbic acid 2-phosphate (AscP) stimulates cellular regeneration in cells exposed to model oxidant tert-butylhydroperoxide (TBHP) (abstract) by stimulating proliferation and cell migration/spreading and decreasing cell death during the recovery period. Appellants argue that Nowak et al only teach that AscP stimulates proliferation and cell migration/spreading and decreasing cell death during the recovery period. This is not persuasive. Nowak et al discloses the instant invention of recovering cellular function following injury (exposure to TBHP) comprising using AscP to stimulate cell proliferation.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

REBECCA COOK
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June 22, 2005

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